

RECEIVED
CENTRAL FAX CENTER

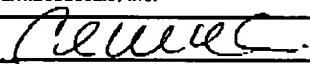
JAN 03 2006


PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM <small>(to be used for all correspondence after initial filing)</small>	Application Number	09/935,318
	Filing Date	8/22/2001
	First Named Inventor	Ching-Leou Teng
	Art Unit	1635
	Examiner Name	Jon Eric Angell
Total Number of Pages in This Submission 79	Attorney Docket Number	ISIS-4824

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks: <u>1 FU</u> The PTO did not receive the following listed item(s) <u>EXT.</u>		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm Name	Isis Pharmaceuticals, Inc.	
Signature		
Printed name	Colleen J. McKiernan, Ph.D.	
Date	<u>Jan 3, 2006</u>	Reg. No. 48,570

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:		
Signature		
Typed or printed name	Laura Eames	Date <u>1/3/06</u>

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

DOCKET NO.: ISIS-4824**PATENT**

of components is clearly stated in the claims which require the combination of drug and bioadhesive in a population of particles. Moreover, having two separate populations of particles allows for the preparation of an oral dosage formulation "in a manner that does not impair the adhesive or release properties of the other" population of particles as discussed in paragraph 0017.

This is clearly distinct from Digenis who teaches a "a hard capsule 10 which is formed from gelatin, starch, or hydrophilic polymer, and which comprises a three compartment delivery system for its pharmacologically active components" (col 9, lines 49-52). The hydrophilic polymer may be hydroxypropyl methylcellulose. As the hydroxypropyl methylcellulose forms the hard outer capsule, it cannot be formed into particles or commingled with the drug as claimed in claim 30. Therefore, claim 30 cannot be obvious in view of the combination of Teng and Digenis. As the remaining claims are dependent either directly or indirectly on claim 30, they are also not obvious in view of the cited references. Therefore the rejection for obviousness over 35 USC 103(a) is overcome.

The newly added claim 41 further states that the populations of carrier particles are released concurrently. This does not further limit the composition of the particles beyond what is claimed, only that the timing of their release from the formulation. As the claim includes all of the limitations of the allowable claim 30, it is also allowable.

FEEs

The Commissioner is hereby authorized to charge \$60.00 to Deposit Account 50-0252 referencing case number ISIS-4824 for a one month extension in time of response, small entity. It is believed that no further fee is due. However, if an additional fee is due, the Commissioner is hereby entitled to charge the Deposit Account listed above referencing this case.

DOCKET NO.: ISIS-4824**PATENT****CONCLUSION**

The Applicants submit that the application is now in proper form for allowance. If the Examiner believes that there are any outstanding issues remaining in the case, he is encouraged to contact the Agent for Applicant listed below to discuss the matter.

Respectfully submitted,



Colleen J. McKiernan, PhD
Agent for Applicant
Registration No. 48,570

Date:

Jan 3, 2006

ISIS PHARMACEUTICALS, INC
1896 Rutherford Road
Carlsbad, CA 92008
Ph: 760-603-2722
Fax: 760-603-3820